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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/724,872	11/28/2000	Gyula Hadlaczky	24601-402F	8394

7590 06/16/2004

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EXAMINER

HELMER, GEORGIA L

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 06/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 09/724,872	Applicant(s) HADLACZKY ET AL.	
	Examiner Georgia L. Helmer	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on 30 March 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1, 4, 6, 7, 9-27, 29-32 and 34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 4, 6, 7, 9, 9-27, 29-32 and 34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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**DETAILED ACTION**

***Status of the Claims***

1. The Office acknowledges receipt of Applicants Response; dated 30 March 2004, and of the 37 CFR 1.132 Declaration of Steven Fabijanski dated 3 March 2004.
2. Claims 1, 4, 6, 7, 9 - 27, and 29 – 32 are pending, and new claim 33 has been added. However a claim 33 already exists in this case. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not). Misnumbered claim 33 been renumbered 34. Claims 1, 4, 6, 7, 9 - 27, 29– 32 and 34 are pending.
3. This action is made FINAL necessitated by Applicant's amendment.
4. All rejections not addressed below have been withdrawn.
5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Information Disclosure Statement***

6. It is noted that Applicant has included reference articles with this Response. However, a proper submission of references must comply with 37 CFR 1.97 and include a filled-out PTO 1449 for consideration by the Office.

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7. Applicant's references submitted with the 7 May 2003 amendment have been entered into the case.

Claim Rejections - 35 USC § 112-second

8. Claims 1, 4, 6, 7, 9 - 27, 29 - 32 and 34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record, which are repeated in part below. To the extent that this is a new rejection, it is necessitated by Applicant's amendment.

The term "satellite artificial chromosome" is unclear. What is a satellite artificial chromosome?

Applicant recites various qualities of an satellite artificial chromosome:

- it contains "satellite DNA" (specification, p. 5). What is "satellite DNA" and how does it differ from other DNA?
- it is a "fully functional stable chromosome" (specification, p. 5).
- it provides an extra genomic locus for targeted integration of DNA (specification, p. 5).
- it is primarily made up of "repeating units of short satellite DNA" and are "nearly fully heterochromatic" (specification, p. 7). What does "nearly fully" mean? 50%? 90%?

However a recitation of properties of a satellite artificial chromosome does not teach what the essential elements of satellite artificial chromosome are, nor does this make the metes and bounds of satellite artificial chromosome apparent.

Applicant traverses saying primarily (Response, p. 7 ¶ bridging to p. 8) that Applicant has discovered something new that no name existed to describe, citing the examples of the first automobile or telephone. Applicant's traversal is unpersuasive. The first automobile and the first telephone were clearly described by drawings and figures and included working models of the inventions.

[I DON'T KNOW WHAT TO SAY ABOUT THE WEIRDNESS OF CLAIM 1]

***Claim Rejections - 35 USC § 112 Written Description***

9. Claims 1, 4, 6, 7, 9 - 27, 29–32 and 34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, for reasons of record. To the extent that this is a new rejection, it is necessitated by Applicant's amendment.

Applicant traverses saying primarily (response, p. 12 ¶ 1) that since the term SATAC is recited in an issued claim (US 6,077,697), this term is presumptively definite.

[Amy- WHAT DO I SAY HERE in response?]

***Claim Rejections - 35 USC § 112.1 Enablement***

10. Claims 1, 4, 6, 7, 9 - 27, 29 – 32 and 34 are rejected under 35 U.S.C. 112, first paragraph, because the claimed invention lacks written description, as

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discussed above. Since the claimed invention lacks written description, one skilled in the art would not know how to make or use the claimed invention.

11. Claims 1, 4, 6, 7, 9 - 27, 29 - 32, and 34 are rejected under 35 U.S.C. 112, first paragraph, for reasons of record. To the extent that this is a new rejection, it is necessitated by Applicant's amendment.

**The Declaration of Fabijanski**

The Declaration of Fabijanski, dated 3 March 2004, has been thoroughly considered and is found not to be commensurate in scope with the scope of the claims.

12. Fabijanski states (Declaration p. 2) states that "using methods and materials described in the... application and standard methods described therein", he and other project scientists have demonstrated that SATAC can be transferred to plant protoplasts, using microcell-mediated fusion of SATAC containing murine (mouse) cells with plant protoplasts, and lipid-mediated transfection of isolated SATAC into plant protoplasts. The Declaration further states that SATACs were introduced into tobacco using microcells prepared from murine cells containing a SATAC.

13. Fabijanski states (Declaration, pages 2-5) that the following experiments have been done by him: (a) the transfer of a mouse SATAC into tobacco cells using microcell-mediated fusion, (b) the transfer of a mouse SATAC into Arabidopsis cells using microcell-mediated fusion, and (c) the transfer of a mouse SATAC into rice protoplasts (using lipid-mediated transfection). Applicant concludes that SATACs can be transferred to plant cells.

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Applicant's traversal has been considered and is unpersuasive. The stated experiments each describe the introduction of a mouse SATAC into plant protoplasts.

14. Fabijanski describes (Declaration, p. 5 last ¶ - p. 10) the “generation of plant artificial chromosomes (Plant SATACs)” by (1) construction of heterologous DNAs—(a) a vector DNA containing a region of homology to tobacco pericentric DNA and a detection marker containing mouse satellite DNA , and (b) a second DNA, the “targeting DNA” containing a region of homology to pericentric DNA sequences; (2) introduction of the DNAs into plant cells and selection—(c) by introduction of Vector DNA and targeting DNA into tobacco protoplasts using transfection, followed by culture of plant tissue microcalli under selective antibiotic conditions. (d) Resulting selected calli were subjected to image analysis using probes specific to the detection marker and to the pericentric sequences. (e) Identification of large scale vector amplification (Declaration, p. 9), followed by (f) overlap image analysis, followed by further analysis.

Fabijanski states (Declaration p.10, 2<sup>nd</sup> ¶ ) that these experiments show “a chromosome breakage product indicating the creation of a plant SATAC”, which contained the plant amplified vector DNA as well as heterochromatic DNA.

The Declaration of Fabijanski, which provides information of the creation of a plant SATAC, is not commensurate in scope with the scope of the claims.

### ***Double Patenting***

15. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

16. Claim 11 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,077,697. The conflicting claims are identical. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

### ***Remarks***

17. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia L. Helmer whose telephone number is 571-272-0796. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0804. The fax



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phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Georgia Helmer PhD  
Patent Examiner  
Art Unit 1638  
June 10, 2004

A handwritten signature in black ink, appearing to read "Amy Nelson", with a stylized flourish at the end.

AMY J. NELSON, PH.D  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600